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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/816,079	03/13/1997	JOHN F. WIRONEN	TB-101	6607

7590 12/21/2001

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EXAMINER

BERMAN, ALYSIA

ART UNIT	PAPER NUMBER
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1619

DATE MAILED: 12/21/2001

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/816,079

Applicant(s)

WIRONEN ET AL.

Examiner

Alysia Berman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of the response to the Notice to File Missing Parts filed September 29, 2001. Claims 1-39 are pending. No claims have been amended.

Continued Prosecution Application

2. The request filed on June 29, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/816079 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "organic osteogenic component" broadens the scope of the claims beyond the scope of the disclosure.

5. Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for demineralized bone matrix, bioactive glass ceramic, $\text{SiO}_2\text{-Na}_2\text{O-CaO-P}_2\text{O}_5$, bioactive ceramic, calcium phosphate ceramic, hydroxyapatite, hydroxyapatite carbonate, corraline hydroxyapatite, calcined bone, tricalcium phosphate, bone morphogenetic protein, TGF- β and PDGF, does not

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reasonably provide enablement for substantially bioabsorbable, organic osteogenic components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Firstly, the specification does not define "organic osteogenic components". One skilled in the art cannot determine from the disclosure what "organic osteogenic components" encompass. Secondly, the definition of osteogenic components in the specification is not exclusive. One skilled in the art is not enabled to determine what bioabsorbable organic components other than those instantly disclosed would be appropriate as a bioabsorbable osteogenic component for use in the instant invention without undue experimentation.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

7. Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 1-39 are indefinite because the independent claims recite "a sufficient period of time to induce bone formation at said site", which renders the claims indefinite. The time period sufficient to induce bone formation is not further defined in the claims or the specification. Therefore, the metes and bounds of the claims cannot be determined.

9. Claims 7-9 recite the limitation "demineralized bone matrix" or "DBM". There is insufficient antecedent basis for this limitation in the claim.

10. Claim 11 recites the limitation "component (ii)" in line 1. There is insufficient antecedent basis for this limitation in the claim.
11. Claims 38 and 39 are indefinite because they contain abbreviations. It unclear what Applicants intend by the abbreviations "DBM" and "BMP". It is suggested that the names of any components be fully written out at the first instance in the claims followed by any abbreviations in parentheses for use in further claims.
12. This application is replete with 35 U.S.C. 112 issues. The above are just some examples. Applicant is required to review all of the claims for 35 U.S.C. 112 issues and make appropriate corrections.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-6, 10-12, 21, 24, 27-30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,191,747 ('747).

US '747 discloses a corrective agent prepared by boiling gelatin in a physiological saline solution to dissolve and sterilize the gelatin (abstract). The gel-forming substance (gelatin) comprises about 0.5% to 30% by weight of the composition (col. 5, lines 29-33). The corrective agent preferably further contains an antibiotic (A) (col. 3, lines 4-5). Substances that stimulate bone formation or bone growth (B) may

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also be added to the corrective agent (col. 3, lines 45-47). These substances include phosphorous, calcium (col. 3, lines 50-53), calcium phosphate hydroxyapatite crystals (col. 4, lines 1-7) and denatured bone meal (col. 4, lines 22-23). See also column 5, lines 48-58 for bone formation or bone growth stimulating substances in an amount from about 2.5-60% by weight (B).

The composition is prepared in disposable syringes and stored at room temperature above that at which the solution solidifies into a gel. It is also possible to cool the solution in the syringes and let it solidify into a gel (col. 6, lines 40-50). Before use, the composition is injected from the syringe into an ampoule at a temperature above that at which the solution solidifies into a gel (col. 7, lines 10-15). However, if the composition in the ampoule is not immediately used, it can be cooled and solidified until needed (col. 7, lines 43-45). Therefore, the prior art appears to read on the limitations of claim 27 of injection molding or extruding the composition and the solidified gel would be the shape of the ampoule, which is tubular or oblong (claim 28).

US '747 discloses at column 2, lines 10-42 that the composition is applied to wound surfaces, used as dental implants and used for open bone fractures, nailings and other bone operations. As stated above, the composition also comprises substances for stimulating bone formation or growth. The composition is used as an implant in bone fractures and other bone related wounds. Therefore, the induction of bone formation is inherent in the method of implanting the composition comprising bone formation stimulating substances.

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The osteogenic components as recited in the claims are not considered a required limitation of the claims because they are recited based on a future intended use. Any properties exhibited by the components of the composition or the composition itself such as gelation temperature or molecular weight are inherent and are not given patentable weight over the prior art composition. Therefore, US '747 discloses a composition comprising gelatin, antibiotics, and bone formation stimulating substances that is implanted into a dental cavity or a bone fracture site and would inherently induce bone formation.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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17. Claims 1-6, 10-12, 21, 24, 27-30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,191,747 ('747).

US '747 teaches all of the limitations of the claims as stated above. It does not explicitly teach a method for inducing bone formation *in vivo*.

Although it is the examiner's primary opinion that the implantation of the prior art composition would inherently induce bone formation, in the case that this may be argued, US '747 teaches that the composition is applied to wound surfaces, is useful as a dental implant and is useful in cases of open bone fractures, nailings and other bone operations as stated above. The composition comprises substances for stimulating bone formation and/or growth.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to implant the composition of US '747 *in vivo* with the reasonable expectation of inducing bone formation. The motivation to use the composition of US '747 to induce bone formation flows logically from the art-recognized desire for implants that sterilely seal wounds and are reabsorbed after bone ingrowth.

18. Claims 7, 8, 13-20, 22, 23 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,191,747 ('747) as applied to claims 1-6, 10-12, 21, 24, 27-30 and 32 above, and further in view of US 5,422,340 ('340).

US '747 teaches all of the limitations of the claims as stated in the 35 U.S.C. 102 and 103 rejections above. It does not teach deriving the gelatin or demineralized bone matrix from the species into which the bone paste is to be implanted (claims 7 and 8), between about 0.001 to 0.1 mg/ml of bone morphogenetic protein (claim 13), a frozen or

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freeze-dried composition (claim 14), from where the gelatin is obtained (claims 15-20), bone growth factor at a concentration of at least 0.001 mg/ml (claim 22), the bone growth factor is morphogenetic protein, TGF-beta, platelet derived growth factor (PDGF) or mixtures thereof (claim 23), the osteogenic components are demineralized bone matrix (DBM), bone morphogenetic protein, TGF-beta or mixtures thereof (claims 33 and 34).

US '340 discloses a formulation for inducing bone formation comprising TGF-beta and tricalcium phosphate. Lyophilized gelatin is disclosed at column 9, line 67. The derivation of components of the formulation from animals such as humans is disclosed at column 11, lines 17-33. The formulations are useful for treating periodontal disease, non-union fractures, spinal fusions, etc. (col. 12, lines 4-19). The formulation is implanted into the animal in the form of a molded implant, etc. (col. 12, lines 34-42). The TGF-beta is mixed with a biodegradable protein carrier such as gelatin to form a carrier matrix. The resultant mixture is dried and formed into an appropriate shape (col. 15, lines 49-54).

Claims 18-20 are not patentable over the prior art product because, although they recite a process by which the product is made, they are directed to the product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method or production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

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unpatentable even though the prior art product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

It is within the skill in the art to select optimal parameters in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). It is also considered within the skill in the art to shape the composition into any suitable form. Therefore, absent evidence of superior and unexpected results, these limitations are not considered critical to the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '747 and substitute the gelatin, bone growth factors and osteogenic components obtained from the animal source and shape the resultant composition into any appropriate shape as taught by US '340 in order to produce a implantable composition for inducing bone formation. The motivation lies in the art-recognized desire for an implantable bone formation inducing composition with enhanced consistency for improved application to the desired bone defect site.

19. Claims 13, 14, 22, 23, 25, 26 and 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,191,747 ('747) as applied to claims 1-6, 10-12, 21, 24, 27-30 and 32 above, and further in view of US 5,484,601 ('601).

US '747 teaches all the limitations of the claims as stated in the 35 U.S.C. 102 and 103 rejections above. It does not teach 0.0001 to 0.1 mg/ml of bone morphogenetic protein (claim 13), a frozen solution or freeze-dried composition (claim 14), that the bone growth factor is morphogenetic protein, TGF-beta, PDGF, or mixtures thereof (claim 23), bone chips (claim 25), bone chips in the size range of 80 microns to 10 mm

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(claim 26), or osteogenic components selected from the group consisting of demineralized bone matrix (DBM), bone morphogenetic protein, TGF-beta, PDGF or mixtures thereof (claims 33 and 34).

US '601 teaches a bone powder composition for use in surgical bone repair (abstract). Bone chips obtained from cortical, cancellous and/or corticocancellous, allogenic or xenogenic bone tissue are disclosed at column 2, lines 3-17. The demineralized bone powder can be stored in a freeze-dried state (col. 2, lines 41-44). For bone morphogenetic proteins and TGF-beta, see column 3, lines 5-6. For gelatin used in the carrier, see column 3, line 63 to column 4, line 6. The example at column 4, lines 55-58 teaches the average particle size of the pulverized bone is about 100 to 300 microns. It is within the skill in the art to select optimal parameters in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). Therefore, the amount of bone morphogenetic protein is not considered critical to the invention, absent a showing of unexpected and superior results. It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '747 and substitute the bone chips, bone morphogenetic proteins and TGF-beta as taught by US '601 in order to produce a bone repair composition. The motivation stems from the art-recognized desire for a composition with a liquid or paste-like consistency that induces new bone ingrowth when applied to a bone defect site.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-44 of copending Application No. 09/014519. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons stated in paper no. 15.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

22. This is a CPA of applicant's earlier Application No. 08/816079. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

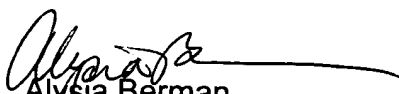
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached during core hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3704 or 703-305-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.


Alysia Berman
Patent Examiner
October 30, 2001


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